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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,043	04/03/2000	BERND EIKMANNS	21437	6651

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EXAMINER	
STEADMAN, DAVID J	
ART UNIT	PAPER NUMBER
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/529,043	EIKMANNS ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *95,100,105,107,108 and 119-121* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *107 and 108* is/are allowed.

6)☒ Claim(s) *95,100,105 and 119-121* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 95, 100, 105, 107-108, and 119-121 are pending in the application.

[2] Applicant's amendment to the claims, filed on 11/28/06, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[3] Applicant's arguments filed on 11/28/06 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[4] The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

[5] Claim(s) 95, 100, 105, and 119-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters-Wendisch et al. (cited as reference AS in the IDS filed on 5/12/2006) in view of Seep-Feldhaus et al. (*Mol Microbiol* 5:2995-3005, 1991) and Han et al. (*Mol Microbiol* 4:1693-1702, 1990).

The claims are drawn to a *Corynebacterium glutamicum* bacterium comprising a vector comprising a nucleic acid encoding SEQ ID NO:2 and methods of microbial production of L-threonine or L-homoserine using a *Corynebacterium* comprising a vector comprising a nucleic acid encoding SEQ ID NO:2.

The reference of Peters-Wendisch et al. teaches a cosmid vector comprising a 40 kb *C. glutamicum* genomic insert, which comprises a 17 kb *Hind*III fragment (translation at p. 2, bottom), which hybridizes to a *C. glutamicum* pyruvate carboxylase gene probe (p. 85, Figure 32). Peters-Wendisch et al. further teaches that *C. glutamicum* "relies especially in the production of amino acids, which derive from precursors of the tricarboxylic acid cycle, on the activity of anaplerotic enzymes" (translation at p. 7, top) and the "pyruvate carboxylase is clearly active as anaplerotic enzyme in *C. glutamicum*" (translation at p. 9, middle). The reference goes on to state, "[i]t was shown a clear effect of the pyruvate carboxylase on the overproduction of lysine with *C. glutamicum,"* particularly as "a defined pyruvate carboxylase negative mutant clearly produces less lysine than the starting strain" (translation at p. 9, bottom).

Peters-Wendisch et al. does not specifically teach a *Corynebacterium glutamicum* bacterium, comprising a vector comprising a nucleic acid encoding SEQ ID NO:2 as encompassed by the claims. Nor does Peters-Wendisch et al. teach a method of microbial production of L-threonine or L-homoserine using such a *C. glutamicum* bacterium.

At the time of the invention, methods for isolating *C. glutamicum* genes encoding proteins having a known function from *C. glutamicum* chromosomal gene fragments were well known in the art. For example, Seep-Feldhaus et al. and Han et al. disclose methods of isolating genes encoding a lysine uptake polypeptide or a threonine synthase gene, respectively, by isolating mutants that complement a lysine uptake-negative mutant (Seep-Feldhaus et al., p. 2996, Figure 1 and right column, top) or a

threonine synthase-negative mutant (Han et al., p. 1694, right column, top and p. 1695, Figure 1) of *C. glutamicum.*

Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of Peters-Wendisch et al. and methods recognized by Seep-Feldhaus et al. and Han et al. to transform the pyruvate carboxylase-negative *C. glutamicum* mutant of Peters-Wendisch et al. with a vector for expressing the 40 kb or 17 kb genomic fragment of *C. glutamicum* as taught by Peters-Wendisch et al. One would have been motivated to do this to confirm the presence of and to isolate the coding region of the *C. glutamicum* pyruvate carboxylase gene on the 40 kb or 17 kb genomic fragment of *C. glutamicum* as taught by Peters-Wendisch et al. by complementation studies as exemplified by Seep-Feldhaus et al. and Han et al. One would have a reasonable expectation of success for transforming the pyruvate carboxylase-negative mutant of Peters-Wendisch et al. with a vector for expressing the 40 kb or 17 kb genomic fragment of *C. glutamicum* as taught by Peters-Wendisch et al. because of the results of Peters-Wendisch et al., Seep-Feldhaus et al., and Han et al. Therefore, claims 95, 100, 105, and 119-121, drawn to a bacterium of the genus *C. glutamicum* comprising a vector comprising a nucleic acid encoding SEQ ID NO:2 and methods of microbial production of L-threonine or L-homoserine would have been obvious to one of ordinary skill in the art at the time of the invention.

If applicant traverses the instant rejection on the ground that the *sequence* of the *C. glutamicum* pyruvate carboxylase gene was not known at the time of the Peters-Wendisch et al. reference, applicant's attention is directed to MPEP 2112.I, which

states, "[i]n *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that 'just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel.'"

If applicant traverses the instant rejection on the ground that the combination of references fails to teach a method for microbial production as encompassed by the claims, it is noted that this is a necessary result of practicing the method as suggested by the combination of references, *i.e.*, 1) transforming the pyruvate carboxylase-negative *C. glutamicum* mutant of Peters-Wendisch et al. with a vector comprising the nucleic acid of Peters-Wendisch et al. and 2) culturing the resulting transformant to express the encoded polypeptide would have inherently resulted in the production of threonine or homoserine by the transformant. Since the Office does not have the facilities for examining and comparing applicants' *C. glutamicum* with the *C. glutamicum* as suggested by the prior art, the burden is on the applicant to show a novel or unobvious difference between applicant's *C. glutamicum* and the *C. glutamicum* of the prior art (i.e., that the *C. glutamicum* of the prior art does not produce L-threonine or L-homoserine, which are naturally produced by the culture of a *C. glutamicum* bacterium). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald* et al., 205 USPQ 594.

Deposit Requirement

[6] Claim 107 (claim 108 dependent therefrom) is drawn to a novel vector contained in the microorganism deposited as DSM 12893. According to the deposit receipt filed 3/1/2005, the microorganism has been deposited under the terms of the Budapest Treaty. Further, applicant's representative has provided a statement that the deposited microorganism will be irrevocably and without restriction or condition released to the public upon the issuance of a patent (3/1/2005 response at p. 6).

Conclusion

[7] Status of the claims:

Claims 95, 100, 105, 107-108, and 119-121 are pending.

Claims 95, 100, 105, and 119-121 are rejected.

Claims 107-108 appear to be in condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656